



LARGE MARKET, SMALL JOINT:

EXAMINING GROWTH, INNOVATIONS, AND M&A IN THE ORTHOPEDIC FOOT AND ANKLE MARKET

Robust innovation in foot and ankle devices is sustaining revenue growth and M&A activity, but in a highly consolidated market, the long-term outlook for new players and ongoing activity is uncertain.

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To those in the orthopedics industry, it is no secret that foot and ankle is currently one of the hottest segments with one of the highest CAGRs—outpacing darlings of the last decade like sports medicine and shoulder replacement. Some of the most vibrant subsegments, such as bunions, hammertoe, and nonfracture ankle treatments, are growing at 9%. The rapid rate of innovation is enabling a dizzying pace of product and company launches in this space, creating challenges for

clinicians in discerning the clinical value of new products from their marketing pizzazz.

The emergence of stand-alone extremity firms, and even more focused foot and ankle companies, in the last few years has led larger, diversified players with portfolio gaps on a rapid M&A hunt. In the last few months alone, we have seen the announcement of at least four major extremity deals (see *Figure 1*).

The public markets are also noticing the enthusiasm with two successful IPOs in recent years—**Treace Medical Concepts Inc.** and **Paragon 28 Inc.**—a rarity for the musculoskeletal (MSK) sector overall, and, specifically, foot and ankle-focused players.

The total ankle arthroplasty (TAA) market, despite a consolidated space solidly owned by **Stryker Corp.**, courtesy of its 2020 acquisition of Wright Medical, and low procedure volumes, saw at least three new implants launched in 2020 alone.

This begs questions: is this growth sustainable, and if so for how long? Is there room for all these products?

The TAA/TAR Market as a Case Study


One interesting microcosm of the foot and ankle market is the TAA/TAR or total ankle arthroplasty/replacement procedure. Volumes have grown at a steady clip of 5-7% in the last five years (excluding 2020) as the technique has been refined and new technologies continue to be developed. New TAA procedures and devices offer improvements over predecessors and arthrodesis (fusion) for ankle osteoarthritis. Most prominently, TAA allows for motion preservation and maintenance of higher activity levels.

However, TAA historically has been a more invasive and complex surgical technique, requiring soft tissue dissection, and has a much higher revision rate than larger joint arthroplasty or ankle fusion. As a result, the procedure has a significant number of contraindications and, to date, physicians have shied away from performing the surgery in younger patients who seemingly would have high demand for it.

The TAA market has been extremely concentrated among top players—particularly with Stryker’s acquisition of Wright Medical—all of which were pioneers in the TAA space. Even with its 2020 divestiture of the historically popular STAR Ankle (and other extremity arthroplasty product lines) to newly renamed **Enovis** (formerly DJO), Stryker controls about 70% of the TAA market (see Figure 2). Which begs the question, how easy is it for new players to break in?

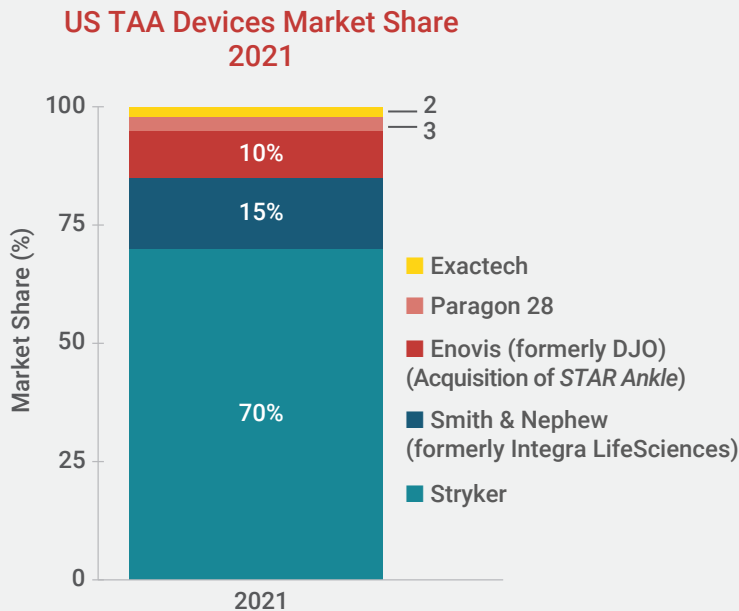
Additionally, despite the market growth, the procedure volumes compared with large joints are quite low. In fact, in 2021, there were only about 10,000 TAA procedures. If we consider that TAA’s available market is the combination of ankle arthrodesis (AA) and current TAA procedures, the total addressable market is just over 20,000 procedures. We are seeing a phenomenon of declining AA rates and increasing TAA rates, so cannibalization of AA is actively occurring

Figure 1
Recent Extremities M&A

ACQUIRER	TARGET	DATE	DEAL VALUE	KEY TARGET PORTFOLIO
 acumed®	 EXSOMED™ <small>Innovations in Hand Surgery</small>	July 2022	Undisclosed	<ul style="list-style-type: none"> • Intramedullary approach for hand fractures
 CONMED	 In2Bones	June 2022	\$145MM \$110MM Growth-based Earnouts	<ul style="list-style-type: none"> • Full portfolio lower and upper extremity fixation systems • Total ankle system • Compression staples • Allograft
 medartis® <small>PRECISION IN FIXATION</small>	 NextremitySolutions®	May 2022	\$70MM	<ul style="list-style-type: none"> • Compression staples • Foot plating systems • Lapidus (bunion) system • Hammertoe system
 DePuy Synthes <small>THE ORTHOPAEDICS COMPANY OF Johnson & Johnson</small>	 CrossRoads <small>Extremity Systems</small>	Feb 2022	Undisclosed	<ul style="list-style-type: none"> • Compression staples • Bunion systems • Foot fusion
 Smith-Nephew	 INTEGRA <small>LIMIT UNCERTAINTY</small>	Jan 2021	\$240MM	<ul style="list-style-type: none"> • Shoulder replacement • Ankle reconstruction • Hand, wrist, elbow, foot recon products

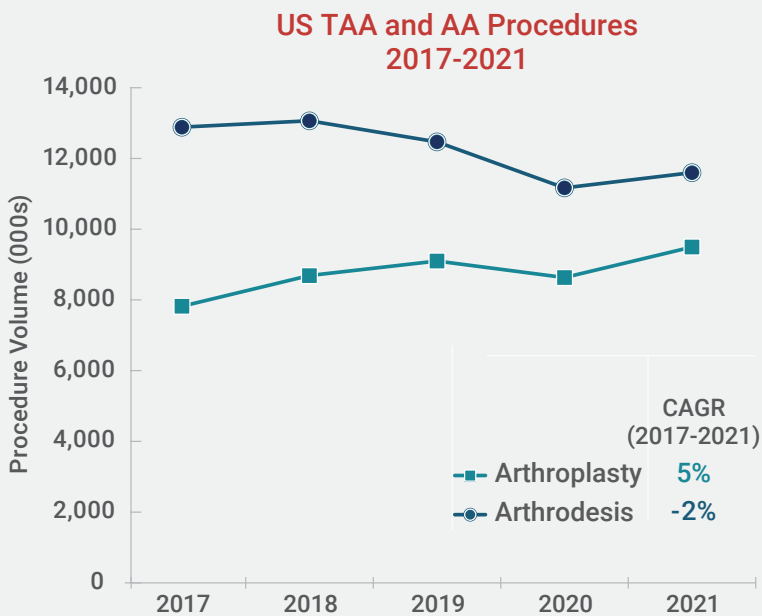
Sources: Health Advances analysis; OrthoWorld; company websites

Figure 2
Total Ankle Market Share



Sources: Health Advances analysis; company reports; Wells Fargo Securities; ONN 2021; OrthoWorld2021

Figure 3
Arthroplasty vs. Arthrodesis Procedure Volume Trends



Note: TAA = Total Ankle Arthroplasty; AA = Ankle Arthrodesis.
Sources: Health Advances analysis; Purple Labs; Definitive Healthcare; 2022 ONN Newsletter; Life Science Intelligence (LSI)

(see Figure 3). Even with relatively high implant costs of \$10,000-15,000 per device, is the market large enough to support all the new players?

The unmet needs, as noted earlier, however, remain high—and, as such, true innovation may be rewarded. In March 2021, the FDA issued a safety communication regarding the STAR Ankle (total ankle replacement system), regardless of date of manufacture. It cited the results of a long-term post-approval study, which showed that the plastic component of the system fractured at a cumulative rate of 13.8% at eight years, and all fractures required revisions or further surgery. These issues may have been associated with multiple factors such as thin plastic liners, or poor patient selection with overly active patients. As such, STAR Ankle’s manufacturer Enovis is planning to undertake updates to the outdated system.

These issues open the door for new products. As an example, in 2020 alone, three new implants hit the already crowded, Stryker-dominated market (see Figure 4). Since then, only Paragon 28 has been able to take appreciable market share (currently ~3%) and edge out MSK giants like Zimmer Biomet. Appropriately so, however, because Paragon 28’s APEX 3D Total Ankle Replacement System is designed to address many of the flaws affecting current TAA. The APEX is a porous 3D-printed implant with customizable sizing intended to reduce or eliminate implant loosening. Additionally, its polyethylene liner is vitamin E infused and highly cross-linked to improve issues with pathological wear.

Smith+Nephew (SNN) also seems successful with its acquisition of Integra LifeSciences Holding Corp.’s extremity line in January 2021. In August of that year, it launched the CADENCE Total Ankle Flat Cut Talar Dome, which allows surgeons to treat a wide range of patients who have varying anatomies and deformities with primary and revision procedures. With further industry consolidation, market shares could continue to shift.

M&A Heats Up

As foot and ankle and other extremity procedures have come into focus, several large OEMs have recognized gaps in their portfolio and are scrambling to acquire companies that offer either differentiated product innovation or help fill gaps in their broader lines. Given the amount of bones in

the feet and the variety of anatomies, the unique combinations of plates and screws needed can cause the required number of SKUs to climb into the thousands. This alone is a huge burden on any one company's R&D engineers, so M&A is a viable route.


Alternatively, the M&A route is also highly attractive to pursue unique "door opening" technologies that may complement an existing extremities portfolio. Both strategies are on display among recent deals.

Among the highlights: **Acumed** just picked up Exsomed, a developer of unique intramedullary nails for hand fracture fixation. Similarly, despite a slightly larger portfolio, CrossRoads Extremity Systems is known for the innovative combinations of its compression staples with miniplates to create unique fixation devices. **DePuy Synthes** was rumored to be after this innovation and the buzz it had created in the physician community, and it acquired the company in February.

Conversely, **ConMed Corp.** and Smith+Nephew each significantly expanded its extremity presence and even entered new extremity markets through the acquisitions, respectively, of In2Bones Global Inc. (June 2022) and Integra LifeSciences' Extremity Orthopedics business.

Based on publicly disclosed deal amounts, valuations are ranging 3-5x revenues for the up-front base value of these

deals. Many of them are too recent to assess their impact on revenues for the acquiring organization, but they are worth keeping an eye on. Will they live up their hype? Is there enough demand in the market to support revenue growth for all these organizations, or are some destined to lose steam while others gain a foothold?

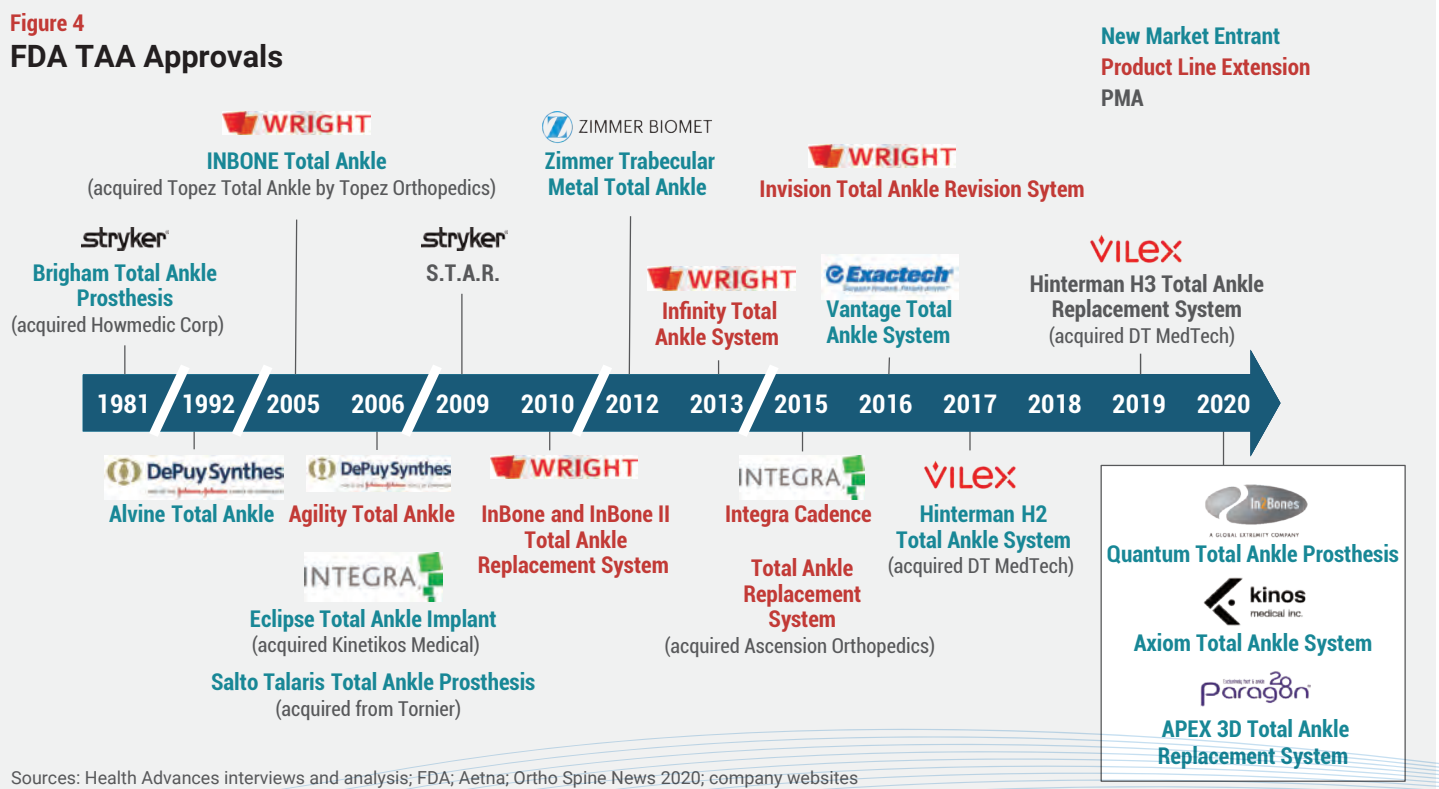
True innovation that improves patient care and outcomes will always have value. Examples here are the total ankle prosthesis that extends longevity to enable utilization in younger patients, and entirely new approaches that revolutionize common procedures, for example, Treace's *Lapiplasty 3D Bunion Correction* for bunionectomy. Time, surgeon experience, and, hopefully, clinical data will distinguish the winners from the losers. 

Posted on MyStrategist.com August 4, 2022



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Figure 4
FDA TAA Approvals



Sources: Health Advances interviews and analysis; FDA; Aetna; Ortho Spine News 2020; company websites